IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LIFEWATCH SERVICES, INC., Plaintiff, v. BLUE CROSS AND BLUE SHIELD ASSOCIATION, WELLPOINT, INC., HORIZON BLUE CROSS BLUE SHIELD OF NEW JERSEY, BLUECROSS BLUESHIELD OF SOUTH CAROLINA, BLUE CROSS AND BLUE SHIELD OF MINNESOTA, and HIGHMARK INC. Defendants.	)	No. 2:12-cv-05146 **JURY TRIAL DEMANDED**

THIRD AMENDED COMPLAINT

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Plaintiff LifeWatch Services, Inc. ("LifeWatch") sues Defendants on the following bases:

ESSENCE OF THE COMPLAINT

1. Blue Cross Blue Shield Association (the "Association") owns the most well-known brand in commercial health insurance nationwide. The Association licenses the Blue Cross and Blue Shield name to about 36 insurers in the U.S. (the "Blue Plans"; together with the Association, "Blue Cross"). The Blue Plans are separately owned companies actually and potentially competing among one another. Collectively, Blue Plans dominate national and regional markets for private commercial health insurance, covering 105 million Americans.

2. Through the Association, the Blue Plans adhere to horizontal agreements that reduce competition in at least two relevant markets:

(a) Commercial-health-insurance market: As sellers of commercial health insurance, the Blue Plans agree not to compete on the overall package of services they offer subscribers; and

(b) The purchase of outpatient cardiac-monitoring devices: The Association and Blue Plans are among the largest purchasers of medical devices and related services in the country. At issue in this case are outpatient cardiac-monitoring devices and Blue Cross has engaged in a concerted refusal to deal in one type of these devices: telemetry. Defendants' concerted action has harmed competition in the outpatient cardiac-monitoring device market.

3. As the largest group of commercial health insurers in the country, Blue Cross has significant power in both of these markets. Blue Cross's collusion has had significant anticompetitive effects in both.

4. In the market for the sale of commercial health insurance, the Blue Cross agreement to offer a largely uniform package of services—a conspiracy that is motivated by cost

savings and masks consumer preference—eliminates incentives to compete for subscribers by offering packages of services that are responsive to consumer demand.

5. In one of the many markets where Blue Cross is a heavyweight buyer, that for outpatient cardiac monitors, Blue Cross's concerted refusal to deal in telemetry devices has distorted the market considerably. Consumers have been harmed by a reduced demand for, and output of, the most advanced and efficacious devices, interference with consumer (doctor/patient) choice, and a reduction in the overall quality of cardiac monitoring.

6. Along with patients, doctors, and other medical-service providers, Plaintiff LifeWatch has been injured by the anticompetitive effects of Blue Cross's agreements. LifeWatch provides telemetry devices and services—telemetry is advanced outpatient cardiac-monitoring used to diagnose irregular heartbeat (cardiac arrhythmia). Telemetry competes with other types of outpatient cardiac monitors but is widely recognized as superior and medically necessary for certain patients and conditions.

7. Blue Cross purports to reconsider its stance on telemetry several times a year. Yet the Blue Plans have adhered in lockstep to blanket denials of coverage for telemetry despite plain and mounting evidence of efficacy and superiority. Because telemetry devices are about three times as costly as the substituted devices, Blue Cross's concerted refusal to deal with respect to telemetry devices puts millions of dollars of additional money into the hands of the Blue Plans.

8. But for their agreement, the Blue Plans would not have monolithically maintained that telemetry is never "medically necessary," or that it is "experimental" or "investigational," which are the positions offered by the Blue Plans to justify their concerted refusal to deal. Over the last decade, scientific and medical literature has exposed this position as increasingly untenable as new studies espousing telemetry's benefits corroborate earlier ones. Such scientific

evidence quickly persuaded Medicare and most commercial insurers to cover telemetry. It is also what has persuaded multiple independent state review panels to overturn Blue Cross denials of coverage in reasoned decisions.

9. Blue Cross's actions deter physicians from prescribing telemetry devices even when a Blue Plan is not the insurer. Due to the dominance of Blue Cross, a doctor deciding on a cardiac monitor might prescribe telemetry only to later receive a patient complaint that the device is not covered. Alternatively, the doctor could review a patient's insurance and discuss financial considerations before deciding to prescribe telemetry. Doctors, who are not paid to do this, avoid this hassle and waste of time by prescribing a less effective but covered monitor from the outset.

10. Doctors' acceptance of and preference for telemetry has nevertheless increased due to the mounting evidence of its efficacy. Blue Cross is able to ignore the resulting pressure to provide coverage because the anticompetitive conspiracy has insulated the Blue Plans from ordinary market forces. Their agreement has thus distorted the markets for both commercial health insurance and outpatient cardiac-monitoring devices, artificially suppressed demand for and output of telemetry devices, artificially inflated the demand for telemetry substitutes, denied patients access to and choice of healthcare services and insurance covering such services, and otherwise harmed competition in ways described below.

THE PARTIES

11. LifeWatch, a Delaware corporation headquartered in Rosemont, Illinois, provides outpatient cardiac-monitoring devices for detecting arrhythmias. Its main product, originally marketed as "Lifestar Ambulatory Cardiac Telemetry," will be referred to as "ACT" herein though it was renamed the "LifeWatch MCT 3-Lead" on January 4, 2016. ACT is a telemetry device. LifeWatch is one of the two largest sellers of telemetry monitors. LifeWatch has patient-monitoring facilities in Philadelphia and near Chicago for privately insured patients. Each

facility serves about half the country; from each facility, LifeWatch personnel analyze data transmitted from LifeWatch's monitoring devices, which are mostly ACT devices.

12. Defendant Association, an Illinois corporation headquartered in Chicago, Illinois, licenses the Blue Cross/Blue Shield trade names and trademarks to approximately 36 Blue Plans, each a separate, locally operated insurer. Blue Plans provide health insurance for approximately 105 million Americans—about one-half of all Americans with private insurance.

13. Defendant WellPoint, Inc. (WellPoint), d/b/a Anthem, is an Indiana corporation, headquartered in Indianapolis, Indiana. WellPoint and its affiliates serve over 71 million people in 14 states—more than 2/3 of all Blue Cross subscribers and more than 1/3 of all privately insured Americans. Specifically, Anthem Blue Cross and Blue Shield plans service (i) Colorado, (ii) Connecticut, (iii) Indiana, (iv) Kentucky, (v) Maine, (vi) most of Missouri (excluding 30 counties in the Kansas City area), (vii) Nevada, (viii) New Hampshire, (ix) Ohio, (x) most of Virginia, and (xi) Wisconsin. In addition: (i) Anthem Blue Cross services California; (ii) Blue Cross and Blue Shield of Georgia serves that state; and (iii) Empire BlueCross BlueShield serves portions of New York.

14. Defendant Horizon Blue Cross Blue Shield of New Jersey (Horizon) is a New Jersey corporation headquartered in Newark, New Jersey. It is the largest health insurer in the state.

15. Defendant Blue Cross and Blue Shield of Minnesota (Blue Minnesota), a Minnesota corporation, is headquartered in Eagan, Minnesota. It has more members, products, and services than any other Minnesota health insurer.

16. Defendant BlueCross BlueShield of South Carolina (Blue South Carolina), a South Carolina corporation, is headquartered in Columbia, South Carolina.

17. Defendant Highmark, Inc. (Highmark), a Pennsylvania corporation, has its principal place of business in Pittsburgh, Pennsylvania. Highmark is one of the largest health insurers in the country, with its affiliates serving members in Pennsylvania, Delaware, and West Virginia.

18. Unsued co-conspirators include other Blue Plans.

VENUE AND JURISDICTION

19. Venue is proper in this district pursuant to 15 U.S.C. §§ 15, 22, and 26, and 28 U.S.C. § 1391.

20. The Court has personal jurisdiction over Defendants, who all do business in this District.

21. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a) and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

Facts Relevant To Venue And Personal Jurisdiction

22. Highmark transacts substantial business in this District through, among other things, its processing of claims for Independence Blue Cross (the Blue Plan for the Philadelphia area); provision of health-insurance coverage to subscribers in 42 counties in western, north central, and eastern Pennsylvania, and 21 counties in central Pennsylvania and the Lehigh Valley; and its transactions with LifeWatch through LifeWatch's Philadelphia monitoring facility.

23. The Association has transacted substantial business in this District through its communications with Independence Blue Cross and Highmark; its administration, control, and licensing of the Blue Cross and Blue Shield trademarks in this District; its marketing of, and negotiation of benefits and premiums for, Blue Cross health insurance to 5.3 million federal

employees and their dependents, including within this District; and its establishment of medical policies affecting subscribers and providers (including LifeWatch) in this District.

24. WellPoint, Blue South Carolina, Blue Minnesota, and Horizon all have transacted substantial business in this District through their transactions with Highmark and LifeWatch's Philadelphia monitoring facility and through use of providers in this District.

Facts Relevant To Subject-Matter Jurisdiction

25. The Defendants substantially engage in interstate commerce and activities substantially affecting interstate commerce:

(a) The Association executes, administers, and controls licensing agreements with Blue Plans throughout the United States, which in turn provide health-insurance coverage for 105 million Americans.

(b) All Blue Plans provide healthcare services in all states for subscribers who are traveling. All Defendants other than Highmark are located outside Pennsylvania and have transacted business with Highmark and LifeWatch, both located in Pennsylvania.

(c) The conspiracy challenged herein involves Blue Plans throughout the United States. The actions pled below, in furtherance of the conspiracy, take place in many states and in interstate commerce.

(d) The actions challenged substantially reduce and distort national and interstate markets for outpatient cardiac-monitoring devices and for health insurance. These actions have reduced the quality of healthcare throughout the United States and the national sales of telemetry and other medical services and devices.

FACTS RELEVANT TO MEDICAL ISSUES

Cardiac Disorders And The Problems They Cause

26. Cardiovascular disease and disorders are the leading cause of death in the United States. The American Heart Association in 2007 published data indicating that one in every three Americans has some type of cardiovascular disease, imposing a cost to the economy of $431.8 billion. Among the most prevalent problems associated with cardiac health in the United States are three relevant to this case: cardiac arrhythmias, atrial fibrillation, and stroke.

27. Cardiac arrhythmias are changes in the heart's normal rate or rhythm and are classified by their speed, rhythm, and location in the heart. Three common and serious problems related to arrhythmias are atrial fibrillation (described next), heart palpitations (incidents of a racing or pounding heart which can signal other serious problems), and syncope (a temporary loss of consciousness sometimes caused by sudden drop in blood pressure).

28. Atrial fibrillation (AF) is recognized as a major source of strokes and a precursor to potentially fatal deterioration of the heart. AF is characterized by a rapid and/or irregular rhythm that can cause serious complications, even death. In the United States:

(a) AF is the most common sustained heart-rhythm disorder. It increases the risk for heart disease and stroke, both leading causes of death, as well as chronic fatigue and congestive heart failure. AF accounts for up to one-fourth of all strokes in the elderly.

(b) AF causes more than 750,000 hospitalizations and an estimated 130,000 deaths each year. Currently, Medicare and private insurers spend billions of dollars annually due to conditions related to AF.

(c) Deaths associated with AF have increased over the past two decades. The prevalence of AF is predicted to increase 2.5-fold during the next 50 years as the population ages.

Outpatient Cardiac-Monitoring Devices

29. Outpatient cardiac-monitoring devices are designed to diagnose and assist in treating arrhythmias. These devices have evolved over time and vary in capabilities and sophistication, but all capture electrocardiographic (EKG) or electrophysiology (EP) information, which displays heartbeat patterns to enable physician diagnosis. The three main types are Holter monitors, event monitors, and telemetry. In rare cases, insertable monitors are also used.

30. Holter monitors. The oldest and simplest cardiac monitor was called a Holter after its inventor. It has been in commercial use since the 1960s. Holters monitor all EKG activity—whether regular or abnormal—over a 24–48 hour period. The Holter does not transmit data. Instead, patients physically return the Holter to their physician for processing and analysis. This process typically results in a delay of a week or more between monitoring and diagnosis. For irregular or infrequent arrhythmias, Holters have a low "clinical yield" (that is, production of a usable diagnosis) of less than 5% (as compared to 88% for telemetry devices).

31. Event monitors (also known as "ambulatory event monitors," AEM, or "cardiac event monitors," CEM; some insurers use the term "event monitor" broadly to include Holter monitors) were developed in the 1980s. Event monitors have two advantages as compared to Holters: they provide longer-term monitoring, generally up to 30 days, and some are able to transmit data telephonically after a cardiac event (arrhythmia) occurs. As compared to Holters, event monitors have the disadvantage of a limited memory and capturing only a "snapshot" of arrhythmic events, not a continuous EKG record. Event monitors fall into three categories.

(a) "Post-event" or "non-looping" monitors record arrhythmic events only after a patient's symptoms start because a patient must activate the monitor and the post-event monitor does not keep a continuous record. These event monitors are often now called "non-

looping event monitors." Because these monitors do not require a patient to wear any leads or wires, they are still used by patients who are unable or unwilling to don the equipment required by other monitors.

(b) Manually triggered "looping" event monitors have one improved feature over their non-looping counterparts: they are able to record all cardiac activity for a preset length of time (typically a few minutes) on a tape that then "loops" so that new input would overwrite previously captured data (similar to recording over a digital file or cassette). When the patient feels an arrhythmia and activates the monitor, the device saves previous seconds (often 30) of recorded data and continues to record subsequent seconds (often 30–60). Manually triggered looping event monitors, as the name suggests, still require a patient to manually start recording; that is, the patient must be both symptomatic and physically able to trigger the recorder (e.g., not a child, dementia victim, or person who faints from arrhythmia). The monitors still have limited memory and still cannot transmit data automatically.

(c) Automatically triggered event monitors, a more recent version, can capture asymptomatic arrhythmia. In most instances, the patient must still manually transmit the data to a monitoring center; monitors still have limited memory; and monitors do not provide continuous information over time of regular and irregular heartbeats.

32. Insertable monitors. For a small number of patients, an insertable monitor is surgically implanted, generally for two years, at considerably greater expense than other monitors. (Telemetry devices average about 3 times the cost of event monitors, insertable devices about 8–10 times as much.) Insertable monitors basically function as long-term automatically triggered event monitors.

33. Mobile-Cardiac Telemetry (herein called "telemetry"), developed in the 1990s, was approved for use by the FDA in 1998 and has been sold since the early 2000s. (Telemetry is also known as "ambulatory cardiac telemetry," "mobile cardiac outpatient telemetry," "cardiac surveillance," MCT, and MCOT.) In December of 2006, LifeWatch began selling its ACT telemetry device, which can record up to 30 days of cardiac data, process it, and quickly provide clinicians with robust, actionable data that aids a physician's interpretation and analysis. ACT, like other telemetry devices, can do the following:

(a) Telemetry devices are programmed with algorithms that automatically detect certain symptomatic and asymptomatic arrhythmia when an arrhythmia occurs. They record both normal and abnormal heart activity (similar to Holters) and can transmit all of the data promptly (like the most advanced event monitors but automatically, immediately, and without need to use a phone).

(b) Telemetry devices can store all of the cardiac data during the time when the patient wears the monitor, resulting in more data collection than Holters and having a greater advantage in this respect when compared to event monitors.

(c) Telemetry devices detect certain arrhythmias based on user-definable input formulae. When a monitored arrhythmia event occurs, the telemetry device automatically and immediately sends a "snapshot" to a 24/7 monitoring facility for analysis. The transmitted results are then interpreted and, if warranted, the patient, her physician, or emergency medical personnel are contacted within minutes. Even if a transmitted event does not warrant immediate notification, the data is stored for trend analysis and a report that is generated at the end of the service.

(d) Telemetry does not require a patient's intervention to either capture or transmit data on an arrhythmia. This decreases the risk of adverse events such as stroke that may occur when a patient has an asymptomatic event. Telemetry automatically captures the beginning and the end of abnormal heart rhythms, including AF.

(e) Because the patient is not required to manually intervene to transmit data from an episode, the time from recording to transmission and subsequent physician notification and intervention is significantly reduced. (In addition, patients may initiate a recording that generates an automatic transmission when they feel symptoms.) If the arrhythmia meets the pre-determined physician notification criteria, monitoring facilities can—as LifeWatch's do—immediately call the physician.

(f) Telemetry services can—and LifeWatch does—allow the physician to order selected portions (in seven-day increments for up to the total time a patient wears the device) of patients' full disclosure EKG recordings in order to understand the early symptoms and etiology of the arrhythmia and determine the ideal therapeutic approach.

34. Comparisons of the three main devices. Since its introduction, telemetry has been widely recognized as the best technology on the market, for some patients and some conditions, in the scientific literature and by experts overturning Blue Cross coverage denials (both detailed below). This recognition rests on the following reasons:

(a) Telemetry is superior to Holters: Telemetry devices are conveniently (and usually) worn for an extended period of time (up to thirty days) and thus are more effective for patients with irregular arrhythmias than are Holters (usually worn 24–48 hours). Telemetry produces a diagnosis in far more cases, perhaps 88%, compared with less than 5% for Holter monitoring.

(b) Telemetry is superior to event monitors: Telemetry provides more actionable data because it compares patients' normal heartbeat with any incidents of arrhythmia and transmits all this information. This additional information gives practitioners a complete picture of cardiac health, leading to better diagnoses and, therefore, better patient outcomes.

(c) Telemetry is superior to both Holters and event monitors: Telemetry automatically and immediately transmits information 24/7 for processing. This feature can greatly benefit low-risk patients with infrequent arrhythmias—that is, those for whom hospitalization is not indicated—but for whom an arrhythmia could be severe or life-threatening. For example, this function could save the life of a patient who has a life-threatening arrhythmia but is unable to call for help. A monitoring facility such as LifeWatch's could alert emergency medical services of the patient's location and peril.

Scientific Evidence On The Efficacy Of Telemetry

35. Even before LifeWatch entered the market in late 2006, an important published study (Joshi et al., 2005) had found telemetry effective in detecting arrhythmia (especially for patients who were asymptomatic during the arrhythmia), well-tolerated by patients, and effective in delivering high-quality data without limiting a patient's activities.

36. Just as LifeWatch was entering the market, in 2007, three important studies were published. Perhaps the most significant peer-reviewed study yet (S.A. Rothman et al., 2007) concluded that "there is reliable evidence that telemetry is superior" to event monitoring technology and that telemetry "provides more effective detection of infrequent cardiac arrhythmias" than other monitoring devices. The Rothman study has been cited approvingly by insurers such as Aetna in explaining why they consider telemetry "medically necessary." No later study has questioned any findings or conclusions of Rothman.

37. That same year, Olson et al., 2007, found that telemetry was more effective than alternative devices for the diagnosis of asymptomatic palpitations, presyncope, and syncope. The study found telemetry potentially effective at assessing the efficacy of a cardiac-drug program, as to which the data from telemetry was used to monitor drug dosage during the monitoring period.

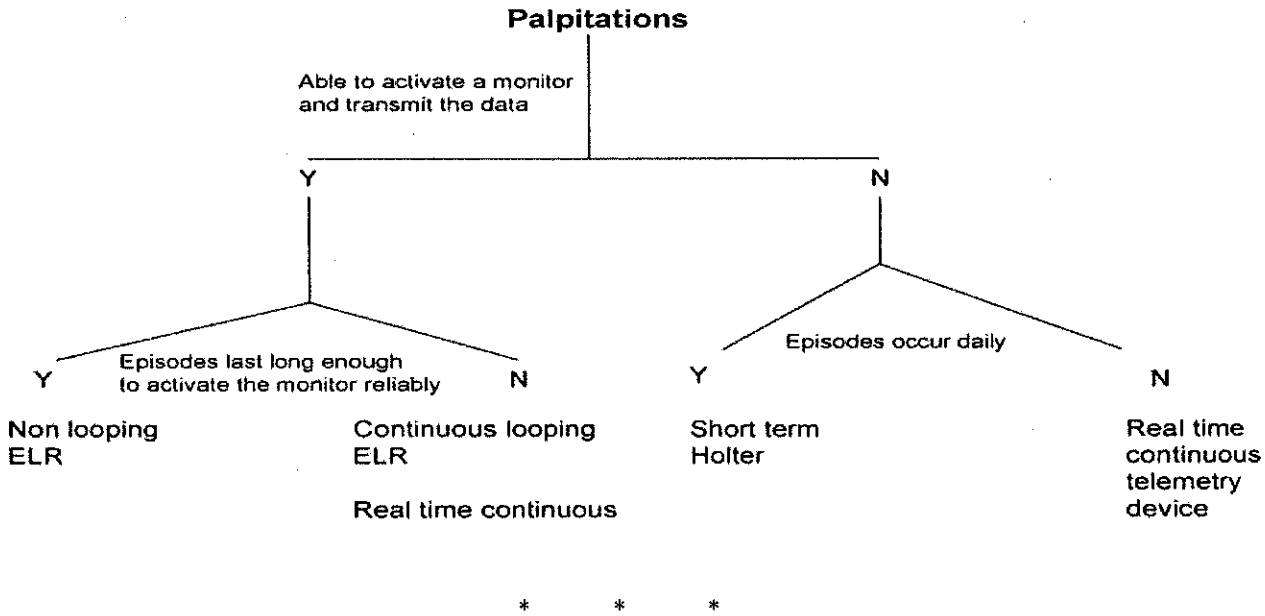
38. Also in 2007, the Centers for Medicare & Medicaid requested a study of telemetry by the Agency for Healthcare Research and Quality (AHRQ). The AHRQ study, relying in part on the Rothman study, which it cited as persuasive, found that patients with syncope or severe heart palpitations were more likely to obtain from telemetry improved diagnoses and/or changes in disease management than if the patients used Holters or event monitors.

39. A pair of 2008 studies (Saarel et al.; Tayal et al.) found that (a) the diagnostic yield from telemetry devices was greater than the historical yield data of telephonic event monitors, and (b) patients at risk of stroke associated with AF might benefit from the real-time capabilities of telemetry, which might lead to more responsive disease management.

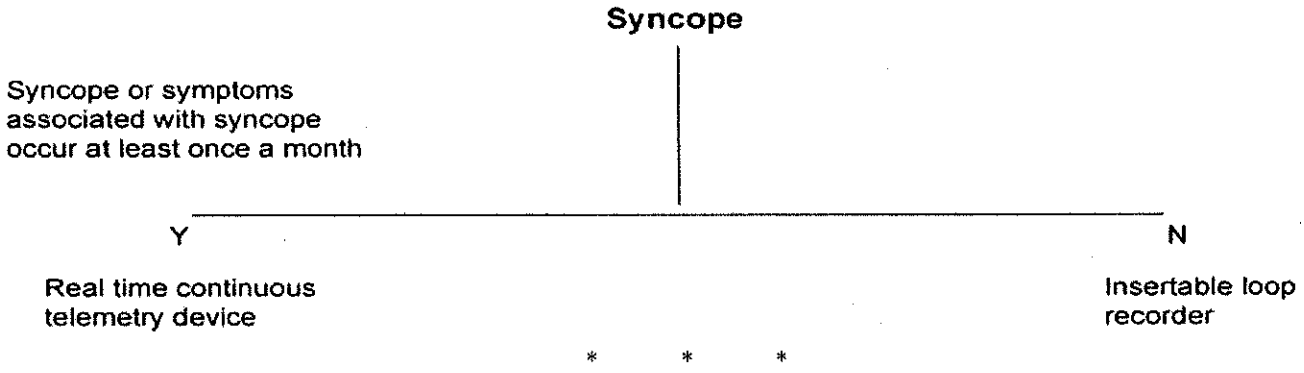
40. A.H. Kadish et al., 2010, concluded that telemetry is potentially life-saving for patients (a) who experience infrequent arrhythmias and who for that reason it is not feasible to hospitalize, and (b) whose symptoms are severe or life-threatening when they occur. The study engaged in a retrospective analysis of 26,438 patients using LifeWatch's ACT device. Kadish found that ACT showed 21% of the patients "had arrhythmic events meeting physician notification criteria during a mean monitoring period of 21 days" and, of those, "262 (1%) had arrhythmic events that could be potentially classified as . . . life-threatening arrhythmic events . . . ." Kadish concluded that "[a]mbulatory cardiac telemetry could be potentially lifesaving in this group of patients."

41. A co-author of the Kadish study, Dr. Harry A. Kopelman, Director of the Cardiac Electrophysiology Laboratory at the Fuqua Heart Center & the Piedmont Heart Institute, applied to ACT the conclusions in the Kadish study (and other prior studies): "Clearly the ACT system supported by the Atrial Fibrillation Post Ablation Patient Care Program is a useful tool in the management of symptomatic and more importantly asymptomatic arrhythmias . . . . The ACT system truly empowers disease state management because of its superior accuracy. The system also allows for safe and cost effective outpatient monitoring and follow-up because of the immediate response protocol . . . ."

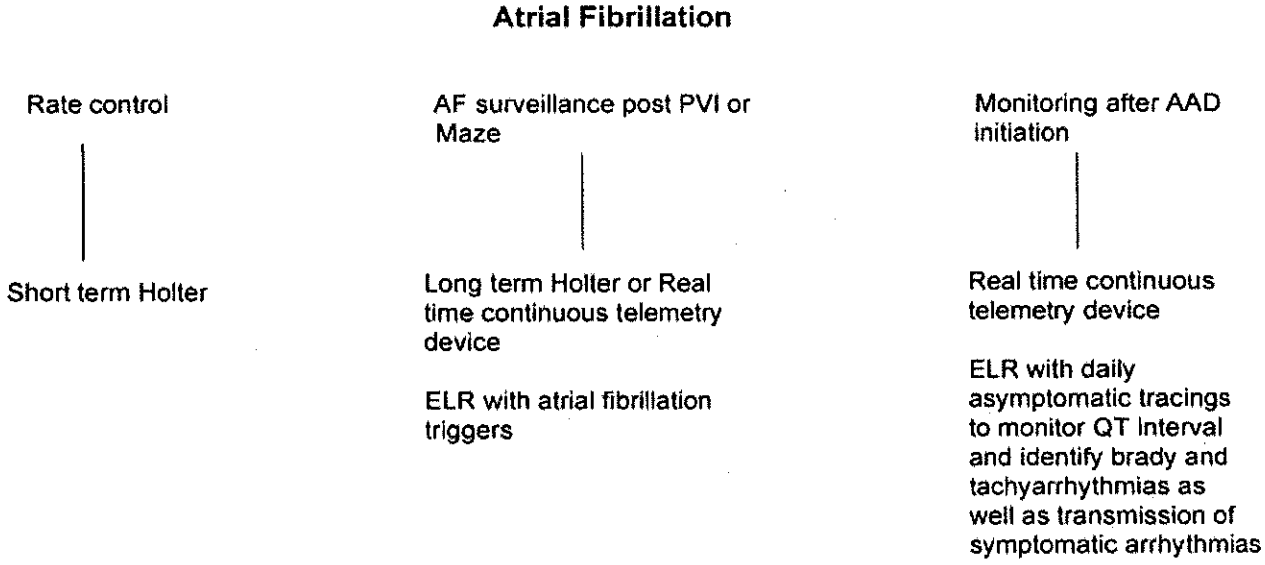
42. In 2010, the American Heart Association sponsored a literature review of available outpatient cardiac-monitoring devices, and discussed the virtues and drawbacks of each (Zimetbaum et al.). As part of this literature review, the authors created the following decision tree to guide physicians on choosing the correct device when (a) a patient had symptoms of (i) palpitations or (ii) syncope, or (b) a patient diagnosed with AF required Antiarrhythmic Drug (AAD) monitoring. On this decision tree, telemetry is the only choice for one palpitation situation and one syncope situation and is a preferred choice for two other situations:


Palpitations
Able to activate a monitor and transmit the data
Y
N
Y
Episodes last long enough to activate the monitor reliably
N
Y
Episodes occur daily
N
Non looping ELR
Continuous looping ELR
Real time continuous
Short term Holter
Real time continuous telemetry device

* * *


Syncope
Syncope or symptoms associated with syncope occur at least once a month
Y
N
Real time continuous telemetry device
Insertable loop recorder

* * *


Atrial Fibrillation
Rate control
Short term Holter
AF surveillance post PVI or Maze
Long term Holter or Real time continuous telemetry device
ELR with atrial fibrillation triggers
Monitoring after AAD initiation
Real time continuous telemetry device
ELR with daily asymptomatic tracings to monitor QT Interval and identify brady and tachyarrhythmias as well as transmission of symptomatic arrhythmias

43. The authors explained these recommendations (emphasis added) (footnotes omitted):

> **Is It Critical to Have Real-Time Access to the Transmitted Rhythms?**
>
> There is an intrinsic appeal to real-time access to potentially serious arrhythmias. This is particularly true for patients who are being monitored for syncope or while starting an antiarrhythmic drug with a potential risk of proarrhythmia. In these instances, rapid access to data could result in clinically significant management decisions, and devices with real-time data access are preferred. . . .
>
> **Obstacles to Compliance With Ambulatory Monitoring Devices**
>
> . . . Failure to activate a device in association with symptoms is a significant problem with monitoring with Holter and standard event records without automatic triggers. In a study mentioned earlier using loop recorders to diagnose syncope, despite patient education and test transmissions, 23% of patients who had recurrence of their syncopal symptoms failed to activate their loop recorder properly.
>
> * * *
>
> **Recommended Approach to Device Selection**
>
> . . . In patients with syncope, we do not routinely use externally applied ambulatory monitoring devices unless symptoms occur relatively frequently. In these cases, we choose a real-time continuous telemetry device as a first choice to allow documentation of asymptomatic rhythms that may provide a clue to the cause of syncope.

44. In 2013, the Heart Rhythm Society, a specialty organization whose mission is to reduce fatalities among arrhythmia patients, found that telemetry "fill[s] a very important role in arrhythmia diagnosis and management."

45. Tsang & Mohan, 2013, found the "diagnostic yield" for patients monitored using telemetry to be significantly higher than for patients monitored using event monitors or Holters. The study found that telemetry improved diagnoses and treatment leading to fewer surgeries and hospitalizations.

46. Defendants probably learned of all these studies no later than shortly after publication (and certainly should have). But despite the evidence, and the fact that Medicare, Medicaid, and other insurers cover telemetry (some, like Medicare, began covering telemetry even before most studies were published), nearly all Blue Plans deny coverage for these services. LifeWatch is not aware of any Defendant reversing such denials or changing their non-coverage position despite the contrary position of all the studies.

Appellate Reversals Of Blue Cross Denials Of Coverage

47. It rarely is cost-effective for any individual patient to challenge a Blue Cross denial of coverage because:

(a) Blue Cross policies typically state that they will pay only for "medically necessary" and "non-investigational" products and services, which are broad, general terms requiring technical interpretation. Blue Cross takes the position that Blue Plans have the contractual right to interpret policy terms subject to review only under an "abuse of discretion" standard.

(b) Blue Cross has a complex three-tier appeal process. The first two tiers, staffed by Blue Cross employees, almost always rule for Blue Cross. A third level of external review (not publicized) exists in some states by law. Some states require such review but allow Blue Cross to choose the reviewer, and Blue Cross almost always prevails in such cases.

48. Given the practical uselessness of the appeal process (surely by design), the only realistic protection for patients, providers, and public health generally is competition. The Blue

Plans that arbitrarily refuse coverage risk losing goodwill, potentially losing customers, and being under competitive pressure to act rationally in making coverage decisions only if each must assess "medical necessity" independently.

49. Notwithstanding the obstacles to appeal—as well as the fact that LifeWatch, under its contract with Highmark, discussed below, was not required to appeal because of Highmark's systematic breach—from 2010 through 2012 LifeWatch challenged some denials (on behalf of patients; providers are not allowed appeal rights by Blue Cross). In these appeals, LifeWatch prevailed overwhelmingly whenever the appeals were decided by independent experts. Those experts often explained (as quoted next) why the scientific studies (summarized above) contradict the Blue Plans' coordinated denial of telemetry as never "medically necessary."

50. North Carolina requires a neutral expert for appeals from denials of insurance coverage. In that state, LifeWatch took eight appeals and prevailed eight times in two years. In one case, on October 3, 2011, the independent review organization MPRO overturned a Blue Cross denial after "[t]he MPRO physician reviewer determined that [telemetry] was clinically necessary."[1] The reviewer found that telemetry "is a cardiac standard of care in cases . . . where the patient's symptoms are clearly not of a frequency that an arrhythmia would likely be captured by other monitoring systems, such as a twenty-four or forty-eight hour Holter."

51. The same organization (MPRO) overruled Blue Cross five more times in ten months. Two other North Carolina independent review boards reached similar conclusions.

52. Michigan also requires that neutral experts review denials. There, the review organization Permedion concluded: "[T]here is sufficient data in the current medical literature

[1] Emphasis added to all appeal decisions quoted in this section.

to establish the superior efficacy of [telemetry. Telemetry] is consistent with the standard of care in this case in the cardiology community."

53. Another Michigan review body, Maximus Federal Services, overturned a Blue Cross denial on July 20, 2010: "Our decision is that Blue Care does have to pay for [telemetry]."

54. The Kentucky State Department of Insurance authorizes Clinix Healthcare to provide independent review of coverage denials. Clinix overruled Blue Cross and concluded that LifeWatch's ACT device "is not experimental. This device is standard of care in the medical community and has multiple peer-reviewed published studies establishing itself as clinically effective." Clinix and another independent review board came to similar conclusions in two other appeals.

55. Blue Plans learned of these appeals (including those quoted above) and their reasoned opinions on the scientific evidence. All Blue Plans that had decided that telemetry was never "medically necessary," or that it was "experimental" or "investigational," adhered to that decision in the face of these reversals.

FACTS RELEVANT TO COMPETITION ISSUES

The Uniformity Rule

56. There is a reason why, for more than a decade, almost all Blue Plans have uniformly held, year after year, that for all patients and all conditions, telemetry is never "medically necessary," despite contrary (a) scientific evidence, summarized above; (b) decisions of independent arbiters, just quoted; and (c) practice of Medicare, Medicaid, and other insurers. The reason is a horizontal anticompetitive agreement, the Blue Cross "Uniformity Rule," as explained in this section.

57. Since 1995, and possibly before that, the Blue Plans agreed among themselves to create what they call a model "medical policy" (their name for directions given to Blue Plan employees on what claims to deny and what to accept). The Blue Plans and the Association also agree to require substantial conformity with this model policy by all Blue Plans (herein referred to as the "Uniformity Rule").

58. To enforce the Uniformity Rule, the Association "audits" each Blue Plan's medical policies. If an audit finds substantial deviations from the model medical policy, the Blue Plan can be penalized and risks losing the right to use the Blue Cross name. To avoid potentially business-ending consequences, all Blue Plans agree to adopt all or substantially all of the Association's coverage decisions, as expressed in the model "medical policy."

59. The Association's model medical policy is set by a Medical Policy Panel, which meets several times a year, generally in Chicago, home of the Association. Each Blue Plan votes as to whether a particular service, procedure, or medical device should be covered.

60. The Defendant Plans have repeatedly voted on the model medical policy that requires blanket denial of telemetry coverage. The model medical policy, entitled "Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry," states (emphasis added):

> Outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered not medically necessary as a diagnostic alternative in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope); this is considered not medically necessary because the clinical (health) outcomes with this technology have not been shown to be superior to other available approaches, yet outpatient cardiac telemetry is generally more costly than those alternative approaches. (See Benefit Application section for contractual items that may impact use in this condition.)
>
> Other uses of ambulatory event monitors, including outpatient cardiac telemetry, are considered investigational, including but not limited to monitoring effectiveness of antiarrhythmic therapy and

> detection of myocardial ischemia by detecting ST segment changes.

61. As noted, this policy is inconsistent with the medical literature; the opinions of the independent experts who specifically rejected the above-quoted position; and the conclusions of other commercial insurers, Medicare, and Medicaid. The position was adopted, year after year for a decade, by 30-plus Blue Plans, not because of an independent evaluation of the evidence, but pursuant to their horizontal agreement to make consistent coverage denials and refuse to deal in disfavored products, such as telemetry. For example:

(a) WellPoint's medical policy states that telemetry is "considered investigational and not medically necessary for all indications."

(b) Horizon's medical policy denying coverage for telemetry is worded almost identically to the Association's national medical policy.

(c) Blue Minnesota states that it treats use of telemetry under any circumstances to be "investigational."

(d) Blue South Carolina's medical policy claims telemetry is "not medically necessary" or "investigational" for all situations.

(e) Blue Cross Blue Shield of Montana, Blue Cross Blue Shield of Wyoming, and Blue Cross of Idaho essentially repeat the Association's policy.

(f) Regence and Blue Cross Blue Shield of Alabama do so but for a few paragraphs.

62. Blue Plans deny coverage for these reasons. For example:

(a) WellPoint denies coverage by claiming that "this service is considered to be not medically necessary."

(b) Horizon denies coverage for telemetry by claiming that the "charges are not covered. Treatment, services or supplies that do not meet our guidelines are not covered under the member's plan."

(c) Blue Minnesota denies coverage for telemetry by claiming that "[p]rocedures determined to be investigational are not covered under the patient's coverage."

Blue Cross's Market Power

63. The Blue Plans are able to dominate many medical service providers, including devicemakers such as LifeWatch, because such providers are often relatively small and highly dependent on a limited number of products. A small company like LifeWatch suffers reduced revenue and profits and sees its incentive to innovate diminished because of Blue Cross's concerted refusal to deal. If a Blue Plan denies coverage, devicemakers are left with no practical recourse: they cannot easily appeal and cannot replace the lost business by dealing with other Blue Plans because they, too, are governed by the Uniformity Rule.

64. Patients have even less recourse. If a patient wants access to a medical device or service not covered under the patient's benefit plan, it is rarely feasible to switch to another employer-sponsored plan that does cover the device. Paying the total cost of the device as an unreimbursed medical expense is, as a practical matter, almost never done. Patients do not have experiences or expectations that foster such decisions. As already explained, appeals of denials are rarely a practical alternative.

65. As noted, the Blue Plans, the largest group of health insurers in the country, insure half of Americans with private insurance—about 105 million subscribers. In some parts of the U.S., a Blue Plan enrolls 90% or more of all private health-insurance purchasers.

66. The dominance of the Blue Plans is unlikely to be challenged by new entrants given high entry barriers that are in part reinforced and perpetuated by Blue Cross. For example:

a new entrant must qualify as an insurer in any state where it wishes to do business, an expensive and time-consuming endeavor. It then must develop in many hundreds of locations broad provider networks of physicians, hospitals, and other medical suppliers. It must obtain from each provider prices competitive with the market's leading incumbents, obviously hard for a new insurer with relatively small initial volume. Insurers must take years trying to build up significant provider networks in many areas, potentially at a large cost, and may not succeed. Another significant barrier to entry relates to the need for name recognition.

67. Blue Plans reinforce and perpetuate these entry barriers:

(a) The Blue Plans cooperate so all offer nationwide coverage, no matter how local the subscriber base of each Blue Plan. Blue Cross's national network includes 96% of hospitals and 92% of doctors throughout the United States. Blue Plans have contracts with more hospitals and physicians than any other insurer. In part for these reasons, Blue Plans dominate not only the sale of insurance but also the administration of self-insured plans. This gives Blue Cross even more market power over providers.

(b) Blue Cross has widespread name recognition. A new plan trying to come anywhere close to such recognition would require costly advertising and marketing and probably even then would not succeed. Such high costs and risk of failure will persuade most investors that there is no significant prospect of a competitive return on investment. Without large and patient investors, there is no way for a new entrant to qualify in states, build a network, and achieve name recognition, all of which take years.

Relevant Markets

68. The Uniformity Rule restrains trade in at least two markets. In the market for the purchase of health-insurance plans (i.e., where the Blue Plans are *sellers*), the Uniformity Rule constitutes a horizontal agreement not to compete based on the package of services offered. The

Uniformity Rule guarantees that all Blue Plans will offer substantially equivalent interpretations of substantially equivalent policies so that, if one does not provide certain coverage, none do.

69. In a second market, for outpatient cardiac-monitoring devices, the Blue Plans are *buyers*. The Uniformity Rule there constitutes a horizontal agreement not to purchase telemetry. The conspiracy's object is to lower the total price paid for outpatient cardiac monitoring. This removes the incentive and ability of individual Blue Plans to make independent determinations about the need or advisability of purchasing a given cardiac-monitoring device. The market for outpatient cardiac-monitoring devices, described at the outset of this fact section, includes Holters, event monitors, telemetry, and—to a degree—insertable devices.

70. Although only those two markets are at issue in this case, the anticompetitive harm caused by the Association and Blue Plans' horizontal agreement is not limited to the purchase and sale of one device, such as a cardiac monitor. Other health services and medical devices, for which the Blue Plans are similarly dominant buyers, are surely also wrongly refused coverage due to the Uniformity Rule in the manner alleged herein. The impact of the Uniformity Rule is thus almost certainly very much greater than what LifeWatch alleges (or needs or intends to prove) in this case. Diminishing competition for other products does further limit, however, the package of services offered consumers.

71. As to the geographic scope of relevant markets, for health-insurance markets there are many.

(a) Regional markets. Insurers in adjacent areas would naturally compete with one another on the package of healthcare services offered.

(b) National markets. The Blue Plans compete for national accounts, that is, subscribing companies with a multistate presence that could choose Blue Plans in various geographic areas and make decisions based on the types of services covered.

72. For devices, the geographic market is national. Telemetry and other monitoring devices can be monitored, handled, and analyzed remotely. LifeWatch handles all work for private American insurers in two monitoring facilities, one near Chicago, the other in Philadelphia. They serve patients and doctors anywhere in the United States with equal ease. All telemetry (and some other monitoring-device) firms in the United States sell outpatient cardiac-monitoring devices nationally.

How The Uniformity Rule Coupled With Blue Cross's Market Power Restrains Competition In The Relevant Markets

73. If each Blue Plan were to make independent decisions respecting coverage, it is implausible that all (or even many) would conclude year after year that, despite mounting and powerful evidence to the contrary, telemetry remains investigational and never medically necessary. Even before 2007, mere common sense and some early studies convinced Medicare and several insurers that telemetry was sometimes "medically necessary" (that is, an effective diagnostic tool meriting coverage). As the weight of the medical studies in and since 2007 accumulated, other insurers came to the same conclusion. From 2010 to 2012, many independent experts concluded that various Blue Plans were plainly wrong and overturned their denials of coverage for telemetry.

74. The Uniformity Rule insulates the Blue Plans from market pressure to pay for telemetry because of Blue Cross's dominant role in the insurance marketplace. Without the coerciveness and pressure of the Association and the Uniformity Rule, the non-covering Blue Plans would not all in lockstep, year after year, have independently decided to refuse coverage of

telemetry for all patients and all situations. In the absence of concerted behavior, the Blue Plans would have felt more acutely the rising demand for telemetry and considered more carefully the medical evidence in its favor. They then would have concluded, like other insurers, Medicare, and Medicaid, that telemetry was and is "medically necessary" for some conditions and patients.

75. The Uniformity Rule also reduces competition in the health-insurance market, in which the Blue Plans agree not to compete on the package of services offered in their benefit plans. The agreement forces consumers to accept lesser benefits and also masks consumer preference for services or devices like telemetry.

76. Because of Blue Cross, doctors prescribe telemetry less often even when competing insurers (such as Aetna) would provide coverage. Because of Blue Cross, physicians deciding whether to prescribe telemetry need to do an insurance analysis (for which no one compensates them) because prescribing without confirming insurance risks patient complaints on discovery that the device is not covered. Blue Cross thus deters doctors from prescribing telemetry even for patients insured by Blue Cross competitors.

77. The Uniformity Rule artificially suppresses demand for, and the output of, telemetry devices and artificially inflates the demand for lower quality, cheaper telemetry substitutes.

78. The Blue Plans' concerted refusal to deal has also interfered with the patient/doctor relationship and consumer choice. Doctors and patients are discouraged from selecting the cardiac-monitoring device best suited for a patient's condition, further harming consumers.

79. Defendants' anticompetitive actions stifle research and development by reducing anticipated future demand for telemetry. Innovation and competition would otherwise result in

higher volume and reduced prices. Competition and consumers are therefore hurt in multiple ways by the market obstructions Blue Cross has created.

80. As evidence of these anticompetitive effects, in 2009 the rates of use of LifeWatch's ACT device per Blue Cross subscriber was 80% higher in an area where telemetry was covered than in the rest of the United States. (See next section for a fuller explanation.)

Highmark's Enforcement Of
The Blue Cross Concerted Refusal To Deal

81. LifeWatch was not much harmed by the Uniformity Rule until March of 2010. From the outset, Blue Cross required LifeWatch (as it requires all providers) to contract for payment only with the Blue Plan covering the area in which a service is performed (in this case, the monitoring of transmitted cardiac data). Unlike most providers, LifeWatch operates remotely. Its two monitoring facilities—in Philadelphia and Chicago—together serve all private-insurance patients in the country. This meant that LifeWatch contracted only with two Blue Plans: Defendant Highmark for the Philadelphia work, and an Illinois Plan for the Chicago work. (LifeWatch settled with the Illinois Plan and thus has not sued it here.)

82. Through early 2010, as required by its contract with LifeWatch, Highmark had been paying all telemetry claims and had not raised issues of coverage because its contract provided that Highmark's medical policy applies, and Highmark is among the tiny handful of Blue Plans that concedes telemetry's medical necessity. (Notwithstanding the Uniformity Rule, some departures from the model medical policy do exist, including Highmark's policy on telemetry.)

83. Under the contract, Highmark paid LifeWatch through February 2010 and, apparently, was reimbursed by patients' home plans (i.e., the Blue Plans that had collected

premiums from non-Highmark subscribers). Such reimbursement arrangements are internal to Blue Cross and are not disclosed to LifeWatch.

84. By March 2010, however, under pressure by other Blue Plans and the Association, Highmark began to refuse to pay telemetry claims submitted on behalf of subscribers to Blue Plans that were not reimbursing for those services.[2]

85. With the Blue Plans now collectively refusing to pay for telemetry (and Highmark playing the critical role of enforcing and implementing this agreement), the market for outpatient cardiac-monitoring devices was dramatically affected: decisions doctors made with their patients were overturned, payments for prescribed devices were rejected, less appropriate devices were substituted for prescribed devices, and prescriptions for telemetry stopped being written, among other impacts.

86. As a result of the Blue Plans' concerted action, payments for prescribed telemetry devices plummeted in 2010 and fewer prescriptions were written then and thereafter. Despite repeated efforts by LifeWatch to have Highmark honor its contractual obligations and pay for telemetry services as required, Highmark refused to do so. By 2012, LifeWatch was forced to stop providing telemetry services under the Highmark contract.

Damages To LifeWatch

87. LifeWatch's harm flows directly from the anticompetitive effects of Blue Cross's collusive behavior and concerted refusal to deal. Telemetry is LifeWatch's core business. As detailed above, Blue Cross distorted the outpatient cardiac-monitoring device market and substantially reduced the demand for and output of telemetry. As a further result of this market

[2] Highmark continued to pay for telemetry for Highmark subscribers. As noted in ¶ 80, above, in 2010-12, Highmark subscribers received 80% more telemetry prescriptions than did patients whose Blue Plans denied coverage.

distortion, doctors' prescription-writing practices have shifted away from telemetry, causing additional harm to LifeWatch. Absent the Uniformity Rule, telemetry would be prescribed more often, paid for more often, and would have a higher margin due to higher volume. This will remain true until Blue Cross ceases to target telemetry with the Uniformity Rule.

88. LifeWatch's revenues and profits had been increasing dramatically until 2009, for example by about 50% from 2008 to 2009. Then, between 2009 and 2012, LifeWatch revenues dropped dramatically. Damages have continued since.

89. To avoid the risk of doctors ceasing to prescribe telemetry entirely because of insurance uncertainty, from March 2010 until April 2012, LifeWatch filled orders for ACT in accordance with the Highmark contract despite not being paid for the services rendered. At the same time, LifeWatch worked out a system so physicians prescribing ACT could authorize LifeWatch to substitute its "Elite" monitor when ACT was not covered. An Elite monitor is essentially an ACT device with functionality disabled or not provided. Elite products are much less profitable in part because a more expensive and capable device is provided for a use less demanding than that which the device was designed to handle.

Lack Of Connection To "The Business Of Insurance"

90. Evaluations of medical evidence and interpretations of such words as "medical necessity" have nothing to do with such aspects of the "business of insurance" as rating schedules, rating classifications, methods of spreading risk, and other activities referenced by the McCarran-Ferguson Act. A horizontal agreement among competitors (a) not to compete over the package of services offered, or (b) to refuse to buy a product, is not unique to the "business of insurance." The same type of illegal agreement could occur in any industry to achieve the same type of anticompetitive ends.

COUNT I:
CONSPIRACY TO RESTRAIN TRADE
IN VIOLATION OF SHERMAN ACT, SECTION 1

91. LifeWatch incorporates here the above allegations.

92. The Uniformity Rule and concerted refusal to deal in telemetry devices are agreements among competitor Blue Plans and the Association.

93. Blue Cross has market power in the health-insurance market and in the market to purchase outpatient cardiac-monitoring devices, nationally and regionally.

94. The Defendants' agreements have caused anticompetitive effects in the relevant markets by distorting the market for outpatient cardiac-monitoring devices and creating an insurance marketplace unresponsive to consumer demand.

95. As such, Defendants' actions have unreasonably restrained trade in violation of Section 1 of the Sherman Act.

96. As a direct and proximate result of the anticompetitive effects caused by Defendants' agreements, LifeWatch has suffered damages of millions of dollars.

97. Defendants will continue their anticompetitive actions and continue to cause damage unless enjoined.

RELIEF REQUESTED

98. WHEREFORE, LifeWatch Services, Inc. prays this Court to grant the following relief:

(a) Permanently enjoin Defendants from entering into, or from honoring or enforcing, any agreements that cause them to act in concert in deciding whether to deny or restrict coverage for telemetry.

(b) Award LifeWatch three times its damages and reasonable costs and attorneys' fees against Defendants, jointly and severally.

(c) Award such other relief, including prejudgment interest, as the facts and law warrant.

JURY DEMAND

99. LifeWatch hereby demands a trial by jury on all issues so triable.

Dated: February 19, 2016

Respectfully submitted,

LIFEWATCH SERVICES, INC.

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One of Its Attorneys

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CERTIFICATE OF SERVICE

I, Michael J. McCarrie, an attorney, certify that on **February 19, 2016**, I caused a true and correct copy of the foregoing **Third Amended Complaint** to be served on the counsel of record listed in the attached Service List via Electronic Mail:

Michael J. McCarrie

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